UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF TEXAS

JEFFERY GREENWELL, on behalf of himself	§		
and all others similarly situated,	§		
	§		
Plaintiffs,	§		
	§		
V.	§	C.A. NO.:	
	§		
	§		
GROUP HEALTH PLAN FOR EMPLOYEES OF	§		
SENSUS USA, INC., BLUE CROSS BLUE	§		
SHIELD OF NORTH CAROLINA	§		
	§		
	§		
Defendants.	§		

ORIGINAL CLASS ACTION COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

JEFFERY GREENWELL, Plaintiff, individually and on behalf of all others similarly situated, files this Original Class Action Complaint (the "Complaint"), pursuant to Rule 23 of the Federal Rules of Civil Procedure, asserting causes of action in law and equity for relief against Defendants Group Health Plan for Employees of Sensus USA Inc. and Blue Cross Blue Shield of North Carolina.

I.

INTRODUCTION

1. This is a class action on behalf of participants and beneficiaries of ERISA plans administered by Blue Cross Blue Shield of North Carolina ("BCBSNC") who were denied Proton Beam Radiation Therapy ("PBRT") because of BCBSNC's uniform application of an arbitrary medical policy to deny as experimental or investigational such treatment for prostate cancer, despite PBRT being recognized for decades by the medical community as an established, medically appropriate treatment for cancer, including prostate cancer.

- 2. Instead of acting solely in the interests of the participants and beneficiaries of its health insurance plans, upon information and belief, BCBSNC denied coverage for PBRT to treat prostate cancer because, on average, PBRT may be significantly more expensive than traditional Intensity Modulated Radiotherapy ("IMRT") or other treatments.
- 3. Plaintiff was a participant in a health insurance plan, Defendant Group Health Plan for EMPLOYEES of Sensus USA Inc. (the "Employer Plan" or "Plan"), issued on behalf of his former employer, Sensus USA Inc., which is a group health benefit plan. The Employer Plan is governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, et seq., and is administered by BCBSNC. Attached hereto as **Exhibit A** is a true and correct copy of the applicable Group Health Plan for Employees of Sensus USA Inc.
- 4. Plaintiff was diagnosed with prostate cancer in June 2015. In early 2016, Plaintiff consulted with physicians at MD Anderson Proton Therapy Center in Houston, Texas, including Dr. Paul G. Corn in the Department of Genitourinary Medical Oncology at MD Anderson. The physicians at MD Anderson recommended that Plaintiff undergo PBRT as an alternative to IMRT because, among other things, the likelihood of achieving a better clinical and post-treatment quality-of-life outcome was greater for PBRT.
- 5. PBRT has been recognized for decades by the medical community as an established, medically appropriate treatment for cancer, including prostate cancer. The FDA approved PBRT in 1988 for the treatment of cancer. The first hospital-based proton-beam center in the United States was at the Loma Linda University Medical Center in Southern California, which began operation in 1990.
- 6. On March 30, 2016, BCBSNC denied Plaintiff's request for prior approval of PBRT on the grounds that (1) it did not meet the Plan's definition of "medical necessity" and (2) fell under the exclusion for "Investigational (Experimental) Services" and (3) BCBSNC's "Corporate Medical Policy: Charged Particle Radiotherapy (Proton or Helium Ion) Investigational (Experimental) Services" ("Medical Policy"), and therefore is not covered for prostate cancer ("PBRT Medical Policy").

- 7. Notwithstanding BCBSNC's denial of coverage, Plaintiff proceeded to have PBRT, with very positive results. Plaintiff paid for the treatment out-of-pocket and sought payment of benefits from BCBSNC. BCBSNC denied coverage. Plaintiff exhausted all internal appeals provided by the Employer Plan. BCBSNC responded by upholding the denial of coverage based solely on the PBRT Medical Policy, and without considering the substantial materials submitted by Plaintiff and his treating providers supporting coverage for PBRT.
- 8. Thereafter, BCBSNC sent Plaintiff to an external appeal with MES Peer Review Services ("MES"), a so-called Independent Review Organization ("IRO") which was unilaterally selected by BCBSNC to conduct the review. MES upheld the denial on the ground that PBRT was not considered medically necessary for Plaintiff and his condition.
- In denying coverage, BCBSNC followed the PBRT Medical Policy, which mandates denial
 of coverage for PBRT to treat "clinically localized" prostate cancer for all plans insured or
 administered by BCBSNC.
- 10. During the external appeal process, MES rubber-stamped BCBSNC's denial decision without conducting a truly independent evaluation of whether PBRT is a proven and effective treatment for prostate cancer.
- 11. As of May 2016, when BCBSNC purported to have most recently reviewed and amended its PBRT Medical Policy during Plaintiff's internal appeals process, the PBRT Medical Policy relied on no new scientific or clinical studies regarding the treatment of prostate cancer with PBRT beyond reference to a 2010 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment for proton therapy. Attached hereto as **Exhibit B** is a true and correct copy of BCBSNC's Corporate Medical Policy: Charged Particle Radiotherapy (Proton or Helium Ion). Simply put, BCBSNC has not considered, even into 2019, any new evidence since 2010 in evaluating the clinical effectiveness and superiority of PBRT for the treatment of prostate cancer.

- 12. BCBSNC's PBRT Medical Policy and resulting denial of PBRT coverage for Plaintiff and Members of the Class he seeks to represent (as defined below) violated the terms of the relevant plans and BCBSNC's fiduciary obligations under ERISA.
- 13. BCBSNC systematically relied on an internally-developed Medical Policy to inappropriately justify applying more restrictive coverage guidelines than allowed for under the plain language of the relevant Employer Plan.
- 14. Plaintiff's Employer Plan required BCBSNC to cover treatment that is "[w]ithin generally accepted standards of MEDICAL CARE in the community." Plaintiff clearly established that PBRT is the standard of medical care in the community for the treatment of prostate cancer and therefore BCBSNC's decision to deny PBRT was contradictory to the relevant language found in the Plan.
- 15. BCBSNC's breach of its fiduciary duties by improperly applying Plan language to claims for benefits forces insureds, like Mr. Greenwell, to pay out-of-pocket for PBRT. Mr. Greenwell was forced to pay \$109,000 out of his own pocket to receive the PBRT prescribed to him by his treating radiation oncologists. Because PBRT provided the best and prescribed course of treatment for Mr. Greenwell, he now brings this action on behalf of the Class Members as well.

II.

PARTIES

- Plaintiff, Jeffery Greenwell, is and was at all relevant times a resident of Grand Prairie,
 Texas.
- 17. Defendant Group Health Plan for EMPLOYEES of Sensus USA Inc. (the "Plan" or "Defendant") is a self-funded group employee welfare benefit plan regulated by ERISA and pursuant to which Plaintiff is entitled to health care benefits. The Plan Administrator is located in Raleigh, North Carolina. Plaintiff is identified by Member ID Number SIPW1609233901.

18. Plaintiff is informed and believes that benefits under the Plan are administered by Defendant Blue Cross Blue Shield of North Carolina ("BCBSNC" or "Defendant").

III.

JURISDICTION AND VENUE

- 19. This action against Defendants arises under 29 U.S.C. §§1132(a), (c), (e), (f) and (g) of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §1001 et seq. This Court has jurisdiction over this action pursuant to 29 U.S.C. §1132(e)(1). Jurisdiction is predicated under these code sections as well as 28 U.S.C. §1331, as this action involved a federal question.
- 20. Venue is proper in this District and Division pursuant to 29 U.S.C. §1132(e)(2) because at all relevant times Plaintiff Jeffery Greenwell was a resident of Grand Prairie, Texas and some or all of the fiduciary breaches for which relief is sought occurred in this district. Defendant Blue Cross Blue Shield of North Carolina also maintains business activities in this district.

III.

GENERAL FACTUAL ALLEGATIONS

A. Proton Beam Radiation Therapy.

- 21. Proton therapy is the most effective form of radiation therapy for many types of tumors. It destroys cancer cells by preventing them from dividing and growing, like conventional X-ray radiation. One of the major differences between proton therapy and conventional X-ray radiation is that protons deposit much of their radiation directly in the tumor and then stop. This allows patients to receive higher doses, which can be more effective, while reducing damage to healthy tissues that surround the tumor.
- 22. The physical properties of protons are different from the physical properties of X-rays. Protons are large, positively charged sub-atomic particles that penetrate matter to a finite depth. X-rays are electromagnetic radiation that penetrates completely through tissue. Protons can be conformed to release much of their energy at precise depths so they can

- target tumors inside the body, depositing much of their radiation exactly at the tumor site. X-rays release their maximum dose of radiation quickly after penetrating the skin, damaging healthy tissue and organs on their way to the tumor and again as they pass through the body beyond the tumor.
- 23. One of the goals of treatment is to deliver the proper dose of radiation to the tumor while limiting the dose received by the surrounding healthy tissue. To deposit the proper amount of energy into the tumor, X-rays must irradiate much of the healthy tissue in front of it, known as an "entrance dose," and they continue to penetrate through the tumor and irradiate much of the healthy tissue behind it, known as an "exit dose." In order to deliver the proper dose to a tumor, a radiation oncologist must "work around" the tumor by using multiple X-ray beams, delivering the highest dose where the beams intersect, but delivering low to medium "entrance" and "exit" doses to surrounding healthy tissue. In contrast, protons enter the patient at a low dose, then, at a precise depth, they deliver a large burst of energy. Immediately after this burst, they stop completely. To treat the entire tumor, additional protons are sent in at lower doses. In this way, protons completely irradiate the tumor while limiting the dose to the nearby healthy tissue. Proton treatment delivers a dose in a more accurate, more efficient way and spares more of the surrounding healthy tissue. Since protons have a low "entrance dose" and essentially no "exit dose," the volume of normal tissue receiving radiation with proton therapy is typically reduced by a factor of 2-3 when compared to even the most modern X-ray treatment plan.
- 24. Proton therapy allows for effective treatment of prostate cancer, while minimizing the radiation dose to vital functions, such as the gastrointestinal system or urinary tract.
- 25. In the late 1970s, imaging advancements coupled with the development of sophisticated computers and improved accelerator and treatment delivery technology made proton therapy more viable for routine medical applications, such as cancer treatment. In 2006, the University of Texas MD Anderson Cancer Center opened the Proton Therapy Center and began treating patients with one of the most advanced and innovative technologies

- available: proton therapy. MD Anderson is currently one of 32 centers of its kind in the United States.
- Many respected cancer facilities and providers, including but not limited to, MD Anderson, Harvard Medical School/Massachusetts General Hospital, Northwestern University, Baptist Hospital's Miami Cancer Institute, Loma Linda University, University of Florida, University of Maryland, Mayo Clinic, Emory University, Case Western Reserve University, Washington University in St. Louis, University of Washington, New York Proton Center, and the Texas Center for Proton Therapy recommend and use PBRT on a regular basis.
- 27. The medical community has found proton beam therapy radiation treatment to be a generally accepted standard of medical practice for the treatment of prostate cancer.
- 28. Other insurers, including Medicare, cover PBRT as a safe and effective prostate cancer treatment that is not "investigational."

B. BCBS of North Carolina is a Fiduciary for its ERISA Plans.

- 29. The majority of health plans underwritten and/or administered by BCBSNC, including the Employer Plan, are employee welfare benefit plans sponsored by private-sector employers governed by ERISA ("ERISA plans").
- 30. BCBSNC is an ERISA fiduciary, as defined by 29 U.S.C. § 1002(21)(A), with respect to Mr. Greenwell's Plan and the plans of all putative Class Members in that BCBSNC interprets and applies ERISA plan terms, makes coverage and benefit determinations under the ERISA plans within its discretion and may provide payment under the ERISA plans to participants/beneficiaries and their providers. Accordingly, BCBSNC was required to comply with the requirements ERISA imposes on fiduciaries.
- 31. The health insurance plans administered by BCBSNC are either fully insured or self-funded. With respect to fully insured plans, BCBSNC both administers the plan by making all benefit determinations and pays the benefits out of its own assets.

- 32. With respect to self-funded plans, BCBSNC administers the plan, but the underlying plan sponsor or employer through which the insurance is provided is ultimately responsible for reimbursing BCBSNC for the benefit payments.
- 33. When processing benefits for a self-funded plan, BCBSNC makes all benefit determinations and authorizes benefit checks to be issued out of bank accounts that BCBSNC controls. Periodically, BCBSNC will notify the sponsors of the self-funded plans of the need to replenish their accounts so that benefits can be paid. But BCBSNC nevertheless continues to control these accounts and is fully responsible for processing the insurance claims and making the determination whether to issue the check from these accounts.
- 34. Thus, irrespective of whether a particular ERISA plan is fully insured or self-funded, BCBSNC is the proper party for Plaintiff, and the putative Class, to sue because BCBSNC—not the underlying plan sponsor or employer—made all the relevant decisions and wielded the authority to issue benefit checks under the ERISA plans.

C. BCBS of North Carolina's Corporate Medical Policy re: Charged Particle Radiotherapy and Business Practices

- 35. BCBSNC drafts, adopts and implements on an annual basis a "Corporate Medical Policy" entitled "Charged Particle Radiotherapy" that relies upon outdated medical evidence, and ignores contemporary medical evidence.
- 36. BCBSNC drafts, adopts and systematically implements this Medical Policy in order to adjudicate insured Members' claims as a replacement for an adequate, full and fair review of member-submitted clinical records.
- 37. BCBSNC drafts, adopts and systematically implements internal policies and procedures for pre-service request (prior approval) review and adjudication of Members' claims that do not provide a full and fair review of clinical records by appropriate medical directors prior to rendering a coverage determination.

- 38. BCBS breaches its fiduciary duties by applying a Medical Policy to Members' claims that is unsupported by contemporary medical evidence and plainly contradicts the standard of care in the medical community.
- 39. BCBSNC has unqualified medical directors, with no experience or training in the context of radiation oncology or who are not board certified in the requisite medical specialty, adjudicate Members' claims and render boilerplate adverse benefit determinations.
- 40. BCBSNC's use of unqualified medical reviewers is a systemic, institutional abdication of its duty to screen, conduct background checks, review available public records through state medical licensing boards, and conduct meaningful interviews of qualified candidates before employing candidates as medical directors who are charged with rendering life and death decisions for Members who seek life-saving treatment under their respective plans.
- 41. By placing this Medical Policy into the hands of medical directors who are not qualified to render opinions as to the medical necessity of PBRT; who lack the education, training and experience to appreciate factors in a given case that indicate the medical necessity for PBT; who are unaware of contemporary medical evidence in the requisite specialty indicating the medical necessity for PBRT; and who follow the inadequate policies and procedures for clinical review, BCBSNC categorically denies all prior approval requests and claims for PBRT for many types of cancers, including prostate cancer.

INDIVIDUAL ALLEGATIONS

A. Mr. Greenwell's Plan

- 42. The Employer Plan is a self-funded plan, meaning that BCBSNC is only responsible for administering the Employer Plan by making all benefit determinations but does not pay the benefits out of its own assets.
- 43. The Employer Plan defines "Covered Services" as ". . . only those services that are MEDICALLY NECESSARY."

- 44. The Employer Plan defines "Investigational (Experimental)" as "The use of a service or supply including, but not limited to, treatment, procedure, facility, equipment, drug, or device that BCBSNC does not recognize as standard MEDICAL CARE of the condition, disease, illness, or injury being treated. The following criteria are the basis for BCBSNC's determination that a service or supply is investigational:
 - (a) Services or supplies requiring federal or other governmental body approval, such as drugs and devices that do not have unrestricted market approval from the U.S. Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.
 - (b) There is insufficient or inconclusive scientific evidence in peer-reviewed medical literature to permit BCBSNC's evaluation of the therapeutic value of the service or supply
 - (c) There is inconclusive evidence that the service or supply has a beneficial effect on health outcomes
 - (d) The service or supply under consideration is not as beneficial as any established alternatives
 - (e) There is insufficient information or inconclusive scientific evidence that, when utilized in a non-investigational setting, the service or supply has a beneficial effect on health outcomes and is as beneficial as any established alternatives.
- 45. If a service or supply meets one or more of the criteria, it is deemed investigational, except for clinical trials as described under this health benefit plan. Determinations are made solely by BCBSNC after independent review of scientific data. Opinions of experts in a particular field and/or opinions and assessments of nationally recognized review organizations may also be considered by BCBSNC but are not determinative or conclusive."

- 46. The Employer Plan defines "Medically Necessary (or Medical Necessity)" as "Those COVERED SERVICES or supplies that are:
 - (a) Provided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease; and, except for clinical trials as described under this health benefit plan, not for EXPERIMENTAL, INVESTIGATIONAL or COSMETIC purposes,
 - (b) Necessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, disease or its symptoms,
 - (c) Within generally accepted standards of MEDICAL CARE in the community, and
 - (d) Not solely for the convenience of the insured, the insured's family, or the PROVIDER.
- 47. The denials at issue in this case relate to BCBSNC's application of the above exclusionary language in its respective plans and its use of the PBRT Medical Policy in denying requests for proton therapy to treat prostate cancer.

B. Denials of Mr. Greenwell's Requests for PBRT

- 48. Plaintiff was diagnosed with prostate cancer in June 2015. In early 2016, Plaintiff consulted with physicians at MD Anderson Proton Therapy Center in Houston, Texas, including Dr. Paul G. Corn in the Department of Genitourinary Medical Oncology at MD Anderson. The physicians at MD Anderson recommended that Plaintiff undergo PBRT as an alternative to IMRT because, among other things, the likelihood of achieving a better clinical and post-treatment quality-of-life outcome was greater for PBRT.
- 49. On March 30, 2016, BCBSNC denied Plaintiff's request for prior approval of PBRT on the grounds that (1) it did not meet the Plan's definition of "medical necessity" and (2) fell under the exclusion for "Investigational (Experimental) Services" and (3) BCBSNC's "Corporate Medical Policy: Charged Particle Radiotherapy (Proton or Helium Ion) Investigational (Experimental) Services" ("Medical Policy"), and therefore is not covered for prostate cancer ("PBRT Medical Policy").
- 50. On April 21, 2016, MD Anderson submitted an internal appeal on Plaintiff's behalf, asking that BCBSNC reconsider its decision to deny coverage or payment for PBRT.

51. On May 20, 2016, BCBSNC upheld its decision to deny coverage. Defendant stated:

This is a request for coverage of proton beam therapy for this patient with T2cN1 Gleason 9 prostate cancer, previously treated with prostatectomy 2015, with recent rising PSA. However, per the CMP of BCBSNC, titled, "Charged Particle Radiotherapy (Proton or Helium Ion"), is considered investigational for this situation. BCBSNC found insufficient peer-reviewed medical literature to show a beneficial effect on health outcomes compared to established alternatives. BCBSNC does not provide coverage for investigational services. Denial is upheld . . . (Emphasis added.)

52. On July 8, 2016, Plaintiff's request for PBRT went before a "Level II Grievance Panel" in which an "external physician board certified in radiation oncology" concluded that PBRT for the treatment of Plaintiff's prostate cancer did not meet the criteria of the BCBSNC PBRT Medical Policy:

Per BCBSNC CMP titled Charged Particle Radiotherapy (Proton or Helium Ion) under the section titled Policy it states, "BCBSNC will provide coverage for Charged Particle Radiotherapy (Proton or Helium Ion) when it is determined to be medically necessary . . . Proton beam radiation therapy is not considered medically necessary due to availability of other available treatment modalities and non-superiority of proton beam radiation therapy compared to other standard options.

- On July 18, 2019, Plaintiff wrote to BCBSNC asking for a reconsideration of their decision.

 This request came after Plaintiff had already exhausted his internal administrative rights under the terms of the Plan.
- 54. BCBSNC interpreted this letter, although the request does not appear to ask for it, as a request for external review.
- 55. On July 21, 2016, BCBSNC sent Plaintiff to an external appeal with MES which was unilaterally selected by BCBSNC to conduct the review. MES upheld the denial on the ground that PBRT was not considered medically necessary for Plaintiff and his condition.
- 56. Importantly, in denying coverage, BCBSNC failed to discuss or even acknowledge the information provided by MD Anderson supporting PBRT, including the many studies verifying its safety and efficacy. Thus, BCBSNC provided Plaintiff with no basis for its negative coverage determination aside from its reliance, to the exclusion of all contrary

- evidence, on BCBSNC's pre-existing policy that PBRT falls under an "investigational" exclusion.
- 57. BCBSNC's decision finding PBRT to be "investigational" and "not medically necessary" under the Employer Plan was erroneous, arbitrary, and capricious.
- Indeed, the Plan's definitions of "Investigational (Experimental)" and "Medically Necessary" confirms that BCBSNC's application of exclusions for PBRT were improper. The definition states that "Investigational (Experimental)" services are services which are supported by "inconclusive evidence that the service or supply has a beneficial effect on health outcomes" or "[t]he service or supply under consideration is not as beneficial as any established alternatives." The definition that a service is "medically necessary" is if it is "[w]ithin generally accepted standards of MEDICAL CARE in the community."
- 59. BCBSNC persistently ignored evidence that PBRT is NOT investigational and has clearly been established as a form of prostate cancer treatment that is within the generally accepted standard of medical care in the community. The internal mechanics of BCBSNC's denials of Plaintiff's request for proton therapy treatment of prostate cancer were replicated for Plaintiff Members' requests for proton therapy treatment of prostate cancer.
- 60. BCBSNC's improper denials forced Mr. Greenwell to pay \$109,000 out of his own pocket to receive the PBRT prescribed to him by his treating radiation oncologists.

C. BCBSNC's Violations of ERISA

- 61. As the claims administrator responsible for interpreting and administering the Employer Plan and similar BCBSNC plans issued nationwide, and vested with responsibility for making final benefit determinations, BCBSNC is an ERISA fiduciary.
- 62. As an ERISA fiduciary, BCBSNC was required to discharge its duties consistent with 29 U.S.C. § 1104, which requires (among other things) that it do so "solely in the interest of the participants and beneficiaries" and for the "exclusive purpose" of "providing benefits to participants and their beneficiaries" and paying reasonable expenses of administering

- the plan. It must do so with the "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. BCBSNC violated all of these requirements.
- 63. BCBSNC violated these duties when it prepared and promulgated the BCBSNC PBRT Medical Policy, because BCBSNC relied upon outdated evidence, ignored evidence indicating that PBRT was not investigational (experimental), and unreasonably concluded that PBRT was "experimental, investigational or unproven." BCBSNC then compounded that breach of duty by relying upon the BCBSNC PBRT Medical Policy to deny insurance claims submitted by Plaintiff and Class Members in contravention of the terms of their BCBSNC plans.
- 64. BCBSNC did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, BCBSNC denied coverage for PBRT to treat prostate cancer.
- 65. In violating its fiduciary duties, BCBSNC elevated its own interests above the interests of plan participants and beneficiaries, reflecting its conflict of interest when determining whether to cover PBRT for prostate cancer. By promulgating and applying its PBRT Medical Policy, BCBSNC sacrificed the interests of insureds like Plaintiff and the Class Members so that it could artificially decrease the number and value of claims it asked its self-funded employer-sponsor customers to pay and prioritized the assets of its employer-sponsor customer. BCBSNC also advanced its own interests in retaining and expanding its business with such customers.

CLASS ACTION ALLEGATIONS

- 66. Plaintiff brings this action individually and on behalf of all others similarly situated as a Class Action pursuant to Federal Rules of Civil Procedure Rule 23.
- 67. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiff seeks certification of a class defined as follows:

All persons covered under ERISA-governed plans, administered or insured by BCBS of North Carolina, whose pre-service or post-service requests for PBRT

were denied at any time within the applicable statute of limitations, or whose requests for PBRT will be denied in the future, based upon a determination by BCBS of North Carolina that PBRT is not medically necessary or is experimental, investigational or unproven.

- 68. The definition of "investigational (experimental)" services or treatment in BCBSNC's health insurance plans at all relevant times has been substantially similar to the definition in the Employer Plan.
- 69. The investigational/experimental exclusion contained in the Employer Plan and relied upon by BCBSNC in denying coverage for Plaintiff is largely identical to, and is interpreted by BCBSNC as having the same meaning as, comparable exclusions included in the BCBSNC plans applicable to all Class Members.
- 70. The PBRT Class excludes (a) BCBSNC, including any entity or division in which BCBSNC has a controlling interest, as well as its agents, representatives, officers, directors, employees, trustees, and other entities related to, or affiliated with BCBSNC, (b) Class Counsel, and (c) the Judge to whom this case is assigned and any Members of the Judge's staff or immediate family.
- 71. Plaintiff and the Class Members reserve the right under Federal Rules of Civil Procedure Rule 23(c)(l)(C) to amend or modify the class to include greater specificity, by further division into subclasses, or by limitation to particular issues.
- 72. This action has been brought and may be properly maintained as a Class Action under the provisions of Federal Rules of Civil Procedure Rule 23 because there is a well-defined community of interest in the litigation and the proposed class is easily ascertainable.

Numerosity

- 73. The potential Members of the proposed class as defined are so numerous that joinder of all the Members of the proposed class is impracticable.
- 74. While the precise number of proposed Class Members has not been determined at this time, Plaintiff is informed and believes that there are a substantial number of individuals covered

- under plans insured or administered by BCBSNC who have been similarly affected.
- 75. Upon information and belief, just last year, approximately 5,000 patients with prostate cancer were treated using PBRT nationwide and across all insurance payors.
- 76. The PBRT Class is ascertainable because its Members can be readily identified using BCBSNC's claims data. PBRT therapy is described with a discrete set of procedure codes under the Current Procedural Terminology ("CPT") promulgated by the American Medical Association. Accordingly, Class Members can be readily and objectively ascertained through use of records maintained by BCBSNC.
- 77. Finally, PBRT Class Members are dispersed geographically throughout the United States, such that joinder of all Members is impracticable.

Commonality

- 78. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(2) and 23(b)(3) because questions of law and fact that have common answers predominate over questions affecting only individual Class Members. These include, without limitation:
 - a. Whether PBRT therapy is an "investigation (experimental)" service or treatment for prostate cancer;
 - b. Whether BCBSNC categorically applied its PBRT Medical Policy to deny coverage to PBRT Class Members;
 - c. Whether PBRT Class Members' claim denials were based in whole or in part on the PBRT Medical Policy.
 - d. Whether the application of the BCBSNC PBRT Medical Policy to Class Members' claims was a breach of BCBSNC's fiduciary duties under ERISA;
 - e. Whether PBRT Class Members are entitled to the relief sought if Plaintiff establishes liability.

Typicality

79. Plaintiff's claims are typical of the claims of PBRT Class Members because Plaintiff was a participant in an ERISA Plan administered by BCBSNC, submitted a claim for coverage of PBRT for treatment of his prostate cancer, and, like other PBRT Class Members, BCBSNC denied his claim for PBRT based on the flawed and artificially restrictive PBRT Medical Policy.

Adequacy of Representation

80. Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff's interests do not conflict with the interests of the Members of the Class. Further, Plaintiff has retained counsel who are competent and experienced in complex class action litigation, and Plaintiff and his counsel intend to prosecute this action vigorously on behalf of the Class Members and have the financial resources to do so. Neither Plaintiff nor his counsel has any interest adverse to those of the Class Members.

Superiority

- 81. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(l) because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications that could establish incompatible standards of conduct for BCBSNC.
- 82. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(2) because by applying a uniform Medical Policy treating PBRT as "investigation (experimental)," BCBSNC has acted and refused to act on grounds that apply generally to the Class, thereby requiring the Court's imposition of uniform relief to ensure compatible standards of conduct towards Class Members, and making final injunctive relief or corresponding declaratory relief appropriate respecting the proposed Class as a whole.
- 83. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(3) because a class action is superior to other available methods for the fair and efficient adjudication of this controversy. Questions of law and fact common to the Class Members predominate over any questions affecting only individual Members.

- A class action is superior to other available methods for the fair an efficient adjudication of this controversy because joinder of all Class Members is impracticable. Further, because the unpaid benefits denied Class Members are small relative to the expense and burden of individual litigation, it would be impossible for the Members of the Class to redress individually the harm done to them, such that most or all Class Members would have no rational economic interest in individually controlling the prosecution of specific actions, and the burden imposed on the judicial system by individual litigation by even a small fraction of the Class would be enormous, making class adjudication the superior alternative under Fed. R. Civ. P. 23(b)(3)(A).
- 85. The conduct of this action as a class action presents far fewer management difficulties, far better conserves judicial resources and the parties' resources, and far more effectively protects the rights of each Class Member than would piecemeal litigation. Compared to the expense, burdens, inconsistencies, economic infeasibility, and inefficiencies of individualized litigation, the challenges of managing this action as a class action are substantially outweighed by the benefits to the legitimate interests of the parties, the court, and the public of class treatment in this court, making class adjudication superior to other alternatives, under Fed. R. Civ. P. 23(b)(3)(D).

IV.

FIRST CLAIM FOR RELIEF

For Denial of Benefits on Behalf of Plaintiff and the Class

- 86. Plaintiffs individually and on behalf of the Class members repeats and re-alleges each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
- 87. This count is brought pursuant to 29 U.S.C. § 1132(a)(l)(B).
- 88. BCBSNC wrongfully denied Plaintiff and the Class Members' claims for PBRT at a time when BCBSNC knew, or should have known, that Plaintiff and the Class Members were due those benefits under the terms of their respective plans.

- 89. BCBSNC failed to provide prompt and reasonable explanations of the bases relied on under the terms of the plan documents, in relation to the applicable facts and plan provisions, for the denial of Plaintiff's and the Class Members' claims for medical benefits.
- 90. BCBSNC failed to properly and adequately investigate the merits of Plaintiff's and the Class Members' medical claims and failed to provide them with a full and fair review pursuant to 29 C.F.R.§2560.503-1 (h)(3)(iii) by failing to consult with health care professionals who have appropriate training and experience in the field of medicine involved in the medical judgment.
- 91. BCBSNC failed to thoroughly and independently evaluate both Plaintiff's and the Class Members' medical records prior to issuing their denials of their claims and their appeals, and failed to provide them with a copy of the internal guidelines relied upon in making the adverse benefit determination, in violation of 29 C.F.R.§2560.503-1 (g)(v)(A).
- 92. Plaintiff is informed and believes that BCBSNC wrongfully denied his claims for medical benefits by other acts or omissions of which he is presently unaware, but which may be discovered in this future litigation and which he will immediately make BCBSNC aware of once said acts or omissions are discovered by him.
- 93. Following the denial of Plaintiff's claims for medical benefits under the Plan, he exhausted all administrative remedies required under ERISA, and he performed all duties and obligations on his part to be performed.
- 94. Plaintiff and Class Members have been harmed by BCBSNC's improper benefit denials because they were deprived of insurance benefits they were owed.
- 95. Plaintiff and Class Members seek the relief identified below to remedy this claim.

V.

SECOND CLAIM FOR EQUITABLE RELIEF

For Declaratory, Injunctive and Other Equitable Relief, and Attorneys' Fees (29 U.S.C. §§ 1132(a)(3), (g))

- 96. Plaintiff individually and on behalf of the Class Members repeats and re-alleges each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
- 97. Defendants act as ERISA fiduciaries with respect to the administration and claims decisions of the group health plans within the meaning of 29 U.S.C. §§ 1109(a) and 1002(21)(A). With respect to these plans, Defendants exercise discretionary authority or control respecting management of the plans, or exercise authority or control respecting management or disposition of the plans' assets. Defendants have the authority, and actually exercise the authority, to fund the plans, or make decisions on claims for benefits and appeals thereof, or write checks for benefits.
- 98. Defendants have categorically and improperly denied requests for PBRT to treat prostate cancer, as alleged above.
- 99. In acting and failing to act as described above, Defendants have breached their fiduciary duties.
- 100. As an ERISA fiduciary, and pursuant to 29 U.S.C. § 1104(a), BCBSNC is required to discharge its duties "solely in the interests of the participants and beneficiaries" and for the "exclusive purpose of providing benefits to participants and their beneficiaries" and paying "reasonable expenses of administering the plan."
- 101. BCBSNC must do so with reasonable "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. BCBSNC must conform its conduct to a fiduciary duty of loyalty and may not make misrepresentations to its insureds.
- 102. BCBSNC violated these duties by adopting and implementing a Medical Policy to deny coverage for PBRT based on investigational exclusions under its plans, when such a finding was contrary to generally accepted practices and to the terms of the plans. In particular, BCBSNC ignored current scientific evidence, and widespread acceptance of PBRT as a safe and effective treatment for prostate cancer in improperly applying the investigational exclusion to PBRT.

- 103. In doing so, BCBSNC did not act "solely in the interests of the participants and beneficiaries" for the "exclusive purpose" of "providing benefits." BCBSNC did not utilize the "care, skill, prudence, and diligence" of a "prudent man" acting in a similar capacity. BCBSNC did not act in accordance with the terms of the Employer Plan and other BCBSNC plans, all of which contain such an investigational exclusion.
- 104. Instead, BCBSNC elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By adhering to an incorrect and outdated Medical Policy with regard to PBRT, BCBSNC artificially decreased the number and value of covered claims thereby benefiting its corporate affiliates and clients at the expense of insureds.
- 105. BCBSNC did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, BCBSNC denied coverage for PBRT to treat prostate cancer due to its average higher cost than traditional radiation treatment throughout the nation. Although the cost of PBRT may be comparable to traditional IMRT in some areas, upon information and belief, BCBSNC nonetheless continued to apply the BCBSNC PBRT Medical Policy uniformly so as to not establish a precedent of covering PBRT only in areas where the cost of PBRT was comparable to traditional IMRT.
- 106. BCBSNC's decision to apply its Medical Policy without any recent clinical developments that acknowledge that PBRT is no longer investigational, demonstrates that BCBSNC arbitrarily applied the BCBSNC PBRT Medical Policy and still does.
- 107. Plaintiff and Class Members have been harmed by breaches of fiduciary duty of BCBSNC because their claims have been subjected improperly to investigational exclusion, leading to denials of coverage for PBRT, when PBRT is actually a Covered Service within the definition of the BCBSNC plans.
- 108. Pursuant to 29 U.S.C. § 1132(a)(3), Plaintiff and the Class Members seek equitable and remedial relief as follows:

- 109. An injunction compelling Defendants to: (1) retract their categorical denials of PBRT for the treatment of prostate cancer; (2) provide notice of said determinations in the form and manner required by ERISA to all BCBSNC subscribers/members who have had requests for PBRT to treat prostate cancer denied; and (3) provide for the re-review of all such improperly denied claims.
- 110. An accounting and disgorgement by Defendants of any profits made by Defendants from the monies representing the improperly denied claims and disgorgement of any profits accrued by Defendants by denying PBRT requests for the treatment of prostate cancer.
- 111. Such other equitable and remedial relief as the Court may deem appropriate; and
- 112. Attorneys' fees in an amount to be proven at the time of trial.

VI.

CLAIM FOR ATTORNEYS FEES & COSTS

113. Plaintiff seeks an award of his reasonable attorneys' fees incurred and to be incurred in the prosecution of this claim. He is entitled to recover those fees, together with his costs of court, pursuant to 29 U.S.C. §1132(g).

VII.

PRAYERS FOR RELIEF

- 114. Plaintiff, individually and on behalf of the Class Members, respectfully prays that upon trial of this matter or other final disposition, this Court find in his favor and against Defendants and issue judgment against such Defendants as follows:
 - a. An Order certifying the proposed Class, appointing Plaintiff to represent the proposed Class, and designating Plaintiff's counsel as Class Counsel;
 - b. An Order declaring that BCBSNC's practices described herein violate ERISA and its ERISA-based fiduciary duties;

- c. An Order requiring BCBSNC to reprocess Plaintiff and Class Members' claims for PBRT to treat prostate cancer in accordance with ERISA-compliant procedures.
- d. An Order requiring BCBSNC to create a common fund out of which it will make payment, with interest, of any unpaid benefits to Plaintiff and the Member Class;
- e. Payment of health benefits due to Plaintiff and the Member Class under Defendants' applicable plans;
- f. Injunctive relief, as described above;
- g. Disgorgement of all profits unjustly retained by BCBSNC as the result of its wrongful denials of PBRT for the treatment of prostate cancer;
- h. Pursuant to 29 U.S.C. § 1132(g), payment of all costs and attorneys' fees incurred in pursuing this action;
- Payment of prejudgment and post-judgment interest as allowed for under ERISA;
 and
- j. For such other equitable and remedial relief as the Court deems just and proper.

Dated: July 19, 2019 Respectfully submitted,

By: /s/ Amar Raval

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ATTORNEYS FOR PLAINTIFF JEFFERY GREENWELL on behalf of himself and all others similarly situated